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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,918	12/14/2000	Azorides R. Morales	P 0266848 UM 1997-35AB	5818

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EXAMINER	
HANDY, DWAYNE K	

ART UNIT	PAPER NUMBER
1743	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

9

Office Action Summary	Application No. 09/735,918	Applicant(s) Morales et al.
	Examiner Dwayne K. Handy	Art Unit 1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-28* is/are rejected.

7) ☒ Claim(s) *3, 8-11, 19, 24 and 25* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *4-6,9*

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Claim Objections

1. Claims 3, 8-11, 19, 24, 25 and 28 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In claims 3, 8-11, 19, 24 and 25 applicant appears to recite intended uses of the device as opposed to further structural limitations on the device. For example, claim 3 recites "the microwave unit of claim 1, wherein the temperature of a solution within the first reaction chamber is maintained between about 50oC and about 70oC". Claim 19 recites the maintaining of a second reactor at a certain temperature. Claims 11 and 12 recite a time for hardening a tissue specimen "wherein the tissue specimen is substantially hardened in less than...". Claim 8 recites the action of bringing the specimen into contact with solutions. As previously stated, these phrases appear to be an intended use of the reaction chamber rather than a limitation on the structural elements of the device. Therefore, appropriate correction is required to place these claims into a format which does not invoke use of the device or the claims should be canceled.

Claim Rejections - 35 USC § 112

2.The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 13, applicant recites the limitation of a "whispering gallery" configuration. This term is unclear. What configuration of elements or structural requirements are necessary to meet this limitation?

Inventorship

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior

art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 3-12, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Essenfeld et al. (WO 99/09390) in view of Carr (5,782,897). Essenfeld et al. teaches a system for the continuous processing of a tissue specimen for histological examination. The overall system is shown in Figure 3 with some of the individual elements pictured in Figures 4-6. The system contains multiple chambers containing solutions which are used in tissue fixation and includes a number of reaction vessels or beakers containing chemicals required for tissue fixation, an agitation unit, a microwave unit and a heater unit. Essenfeld recites solution materials contained in the reactors in the Examples. In Example 3, for instance, the following solutions are disclosed:

- a solution of a ketone and alcohol at a 1:1 – 6:1 volume ratio and a polymer of 100-500 MW (p. 27, lines 16-21)
- a solution of a ketone and alcohol with the concentration of ketone lower than the alcohol (p. 27, lines 29-31)
- a solution of a mineral oil, ketone and alcohol (p. 28, lines 6-8)
- a wax solution (p. 28, l. 19-23)

The heating and agitation units are disclosed on page 17, lines 24 through page 18, lines 28. Temperature ranges of 50-70°C are disclosed in the Examples. Essenfeld does not

teach a microwave radiation source which transmits radiation directed via a waveguide at the specific frequency cited by applicant in the instant claims. Carr teaches a microwave heating apparatus for rapid tissue fixation. The device is best shown in Figure 1 and described in columns 3-5. The device (10) contains a generally rectangular waveguide resonator (12). The resonator receives power from a conventional microwave source and is sized to optimize propagation of microwave energy to the tissue sample. An aperture (16) is provided in the resonator (12) as a narrow slot which permits insertion of a sample holder (18) containing a tissue sample into the heating region (14). The sample holder is positively supported in the heating region by a slab (22) of dielectric material. In describing the operation of the device in column 6, Carr discloses that the device operates at a frequency of 2.45GHz. In columns 1 and 2, Carr discloses the advantages of his device over conventional microwave ovens. From column 1, line 63: "the early microwave apparatus are disadvantaged because they heat the sample in a non-uniform manner so that some areas of the tissue may become overheated and be destroyed, while other areas may not become fixated at all. The use of a carousel to move the sample within the microwave field alleviates this problem to some extent, but makes it more difficult to position the samples and to automate the fixation process. Also, a microwave oven operates inconsistently because its fields constantly change throughout the oven. These changes cause different heat patterns within the sample each time the sample is fixated. Such inconsistencies can cause error in the analysis". It would have been obvious to one of ordinary skill in the art, then, to combine the teachings of Carr with the tissue processing system of Essenfeld. Essenfeld

already teaches the use of a microwave unit for tissue fixation. One would employ the waveguide of Carr with the modified microwave of Essenfeld to avoid the problems with conventional microwaves as stated in the reference and cited by the Examiner above including non-uniform heating which leads to tissue damage, a lack of fixation of certain areas of the tissue, or inconsistencies in the sample due to uneven energy in the microwave.

7. Claims 15-17 and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Essenfeld and Carr, as applied to claims 1, 3-12 and 14 in paragraph 6 above, and further in view of Bernstein et al. (5,875,286). Essenfeld and Carr, as applied in paragraph 6 above, teach every element of claims 15-17 and 19-25 except for the conveyance which transfers the tissue specimen between modules comprised of a track or armature. Bernstein teaches an automated system for examining fixated tissue. The automated system includes a robotic arm which moves along a track for conveying the tissue specimen through the system. The robotic arm and conveyance track is shown in Figures 1 and 2. It would have been obvious to one of ordinary skill in the art to combine the teaching of the robotic arm with the system of Essenfeld. The addition of the robotic arm element would automate the system and speed up processing time.

8. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Essenfeld and Carr, as applied to claims 1, 3-12 and 14 in paragraph 6 above, and further in view of Grillo et al. (6,011,247). Essenfeld and Carr, as applied paragraph 6 above teach every element of

claims 26-28 except for the fluid communication between the storage chambers and the reaction chamber in the microwave. Grillo et al. teaches a system which may be used for open and/or closed vessel microwave chemistry. The system includes a microwave unit (1) with feed line (15) for feeding reactants to the vessel (3) contained inside. The feed line (15) is connected to containers (14) of a reagent dispenser (5) The dispenser is controlled by the processor (6) and includes a valve and pumps for controlling the dispensing elements. (

Grillo also teaches that the vessel may contain a cooling channel that includes "a sleeve or coating of metal (or other microwave reflecting material)". The Examiner considers this to be thermal insulation that surrounds the reaction chamber. It would have been obvious to one of ordinary skill in the art to combine the teachings of Grillo with the combined teachings of Essenfeld and Carr. The addition of the dispensing system would allow the operator to add reactants to the reactors in the microwave without having to remove the reactors from the microwave. This would speed processing time. The addition of insulation would keep the reactors from becoming overheated and would keep the outside of the reactor cool to the touch of the operator when removing the vessels from the microwave.

9. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Essenfeld, Carr, and Bernstein et al., as applied to claims 15-17 and 19-25 in paragraph 7 above, and further in view of Grillo et al. (6,011,247). Essenfeld, Carr, and Bernstein et al., as applied in paragraph 7

above teach every element of claim 18 except for the thermal insulation around the reaction chamber. Grillo et al. teaches a system which may be used for open and/or closed vessel microwave chemistry. The system includes a microwave unit (1) with feed line (15) for feeding reactants to the vessel (3) contained inside. Grillo also teaches that the vessel may contain a cooling channel that includes "a sleeve or coating of metal (or other microwave reflecting material)". The Examiner considers this to be thermal insulation that surrounds the reaction chamber. It would have been obvious to one of ordinary skill in the art to combine the insulation of Grillo with the combined teachings of Essenfeld, Carr, and Bernstein. The addition of insulation would keep the reactors from becoming overheated and would keep the outside of the reactor cool to the touch of the operator when removing the vessels from the microwave.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lauf et al. (6,268,596) disclose am apparatus and method to concentrate microwave power to a liquid sample being processed. Mutterer, Jr. et al. (6,258,329) teach a system for carrying out microwave assisted reactions in vessels. Login et al. (4,994,237) show a microwave system for preserving and sterilizing tissues.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (703)-305-0211. The examiner can normally be reached on Monday-Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703)-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703)-772-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0661.

Jill Warden
Supervisory Patent Examiner
Technology Center 1700

dkh

March 21, 2003